

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: [Ohio Department of Public Safety \(DPS\) - Division of Emergency Medical Services \(EMS\), State Board of Emergency Medical, Fire, and Transportation Services](#)

Regulation/Package Title: [Reporting Delivery of Emergency Medical Services Trauma Care](#)

Rule Number(s): [O.A.C. Rules 4765-4-01, 4765-4-02, 4765-4-03, 4765-4-04, 4765-4-05, 4765-4-06, 4765-4-07, 4765-4-08, 4765-4-09](#)

Date: [August 22, 2017](#)

Rule Type:

New

☒ Amended

☒ No Change

☒ 5-Year Review

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

Chapter 4765-4 of the Administrative Code (OAC) amplifies section 4765.06 of the Revised Code (RC) and specifies the methods and standards for maintaining and reporting data collected on the delivery of emergency medical services and trauma care by emergency medical services agencies and hospitals. Pursuant to a scheduled 106.03 five-year rule review, EMS proposes to file six of the nine rules in Chapter 4765-4 as "no change" rules and to amend three of the rules. Proposed amendments include: paragraph (I) of OAC 4765-4-01 is amended to address material incorporated by reference; paragraph (D)(1) of rule 4765-4-04 is being amended to become paragraphs (D)(1) and (D)(2) to eliminate a (1) that is not followed by a (2); and paragraph (B)(1) of rule 4765-4-06 is being combined with paragraph (B) to eliminate a (1) that is not followed by a (2).

A summary of each of the nine rules included in OAC Chapter 4765-4 is:

4765-4-01	AM	Definitions.	This rule sets forth the definitions for terms used in Chapter 4765-4 of the Administrative Code.
4765-4-02	NC	Purpose.	This rule sets forth the reasons for comprehensive reporting of clinical data.
4765-4-03	NC	Required reporting.	This rule identifies which entities are required by section 4765.06 of the Revised Code to report clinical data and sets the minimum information to be collected from each entity.
4765-4-04	AM	Risk adjustment.	This rule defines risk adjustment and specifies certain methodologies for risk adjustment that must be used before clinical data can be made public or released in response to a public records request.
4765-4-05	NC	Protected information.	This rule defines how clinical data collected as required by Chapter 4765-4 of the Administrative Code shall be protected and sets forth what clinical data cannot be made public or provided in response to a public records request.
4765-4-06	AM	Submission of data.	This rule sets forth the format for submission of clinical data and the method of transmission of clinical data.
4765-4-07	NC	Reporting deadlines.	This rule sets forth the deadlines for the submission of clinical data that is required to be submitted and allows for the State Board of Emergency Medical, Fire, and Transportation Services (EMFTS) to develop and post policies to grant extensions to those deadlines.
4765-4-08	NC	Failure to report.	This rule sets forth the consequences for an entity should that entity fail to report as required by Chapter 4765-4 of the OAC.
4765-4-09	NC	Regional reporting.	This rule permits entities to submit clinical data to the trauma registry through a regional trauma registry rather than directly to the clinical data systems.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Section 4765.11 of the Revised Code.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

The regulations do not implement federal requirements, nor are they being adopted to participate in a federal program.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

N/A

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

Pursuant to RC section 4765.06, both the EMS and trauma data systems exist to study and improve the delivery of care to ill and injured people in Ohio. This regulation specifies and standardizes data reporting methods in order to ensure consistent, coherent data is received for study.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

OAC Chapter 4765-4 has served well to provide clear, easily understood standards for reporting of required data. Stakeholders who report data have found these regulations to be helpful. Additionally, multiple scientific studies using the data in the data systems covered by these rules have been published. Continued contributions to the body of scientific knowledge will also be used as a measure of success.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

Stakeholders include members of EMFTS Board and members of the Division of EMS staff and DPS legal staff. In addition, members of the Trauma Committee advised EMS during the rule review process. The Trauma Committee of the State Board of EMFTS is established in section 4765.04 of the RC to advise and assist the EMFTS Board in all matters regarding trauma care and the Ohio Trauma System. The State Board of EMFTS is established pursuant to section 4765.02 of the RC. EMFTS board members are nominated by organizations including:

- the Ohio Ambulance and Medical Transportation Association,
- the Ohio Association of Critical Care Transport,
- the Ohio Association of Emergency Medical Services,
- the Ohio Association of Professional Firefighters,
- the Ohio Chapter of the American Academy of Pediatrics,
- the Ohio Chapter of the American College of Emergency Physicians.
- the Ohio Department of Public Safety,
- the Ohio EMS Instructor Coordinator Society,
- the Ohio Fire Chiefs' Association,
- the Ohio Hospital Association
- the Ohio Osteopathic Association, and
- the Ohio State Firefighters Association.

Additional organizations, represented by members of the Trauma Committee, include: the Alliance of Ohio Trauma Registrars, the Ohio Committee on Trauma (American College of Surgeons), and the Ohio Society of Trauma Nurse Leaders.

In January 2017, the OAC 4765-4 rule numbers and tag lines were posted at the EMS Small Business Regulatory Impact Web site (http://www.publicsafety.ohio.gov/ems_rules.stm) under the heading “Rules Scheduled for Review.”

EMS administration and trauma and research staff members were provided with copies of the OAC 4765-4 rules and a proposed filing schedule in November 2016, January 2017, and March 2017.

Members of the Trauma Committee of the State Board of EMFTS received copies of the OAC 4765-4 rules and proposed filing schedules on April 17, 2017 and discussed the rules during their May 10, 2017 and July 12, 2017 meetings. No changes were recommended. Members of the State Board of EMFTS received copies of the OAC 4765-4 rules and proposed filing schedules as part of the board packets in advance of the April 19, May 24, June 21, and August 16, 2017 board meetings. The EMFTS Board received a Trauma Committee report at the April 19, June 21, and August 16, 2017 board meetings.

Stakeholders copied on the rules and Business Impact Analysis (BIA) filed with Common Sense Initiative (CSI) office include:

- the Ohio chapter of the American college of emergency physicians (ACEP);
- the Ohio chapter of the American college of surgeons (ACS);
- the Ohio chapter of the American academy of pediatrics;
- OHA: the association for hospitals and health systems;
- the Ohio osteopathic association; and
- the association of Ohio children's hospitals.

When the rules are filed with CSI, govdelivery.com will be used to notify approximately 480 trauma system and 150 Ohio trauma registry subscribers about the OAC Chapter 4765-4 filing and stakeholder comment period.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

EMS staff proposed two changes related to formatting (OAC rules 4765-04 and 4765-06) and one amendment related to materials incorporated by reference (rule OAC 4765-4-01).

Members of the Trauma Committee of the State Board of Emergency Medical, Fire, and Transportation Services (EMFTS) reviewed the rules and proposed amendments and the draft Business Impact Analysis (BIA) prior to the Committee’s July 12, 2017 meeting. At the July 12 meeting, the Committee voted to recommend the draft rules and BIA to the EMFTS Board for approval and submission to the Common Sense Initiative Office and the Joint Committee on Agency Rule Review. The EMFTS Board approved filing the OAC 4765-4 rules and BIA with the Common Sense Initiative (CSI) office at its August 16, 2017 meeting.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

There is no scientific data to be considered.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

No alternatives were considered, as the State Board of EMFTS is required by RC section 4765.06 to create the data systems set forth in these rules. These rules simply set the standards for the reporting of data to those statutorily prescribed systems.

11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

EMS considers these performance-based regulations. The rules do not prescribe specifications for how EMS agencies and hospitals collect, process, and report their data to the data systems. These rules establish standards for which data is needed to consistently monitor the EMS and trauma systems, as well as deadlines for timely submission of that data.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

As EMS is the only division statutorily directed to administer these systems, a review of RC Chapter 4765. and OAC Chapter 4765 was performed. Additionally, EMS has not received any stakeholder complaints of duplication in the fifteen-plus years of these systems' existence.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The revisions proposed for OAC 4765-4 rules are to improve formatting and update the information about a reference to the Code of Federal Regulations (C.F.R.). No substantive or procedural changes are proposed to the rules, which have been in effect with no significant amendments since May 2003 or earlier.

The Division of EMS posts information about the rule review process, including those rules scheduled for review, drafts open for public comment, proposed rules and public hearing notices, and recently adopted rules, at its *Small Business Regulatory Impact* Web site (http://www.publicsafety.ohio.gov/ems_rules.stm). The laws and rules associated with trauma care are provided as links at the *EMS Trauma System* Web site (<http://www.ems.ohio.gov/trauma-system.aspx>), and the amended rules, when they become effective, will be available through that link. The Division of EMS will use the EMS.gov.delivery.com system, which includes a *Trauma System* subscribers list of approximately 480 addresses and an *Ohio Trauma Registry* subscribers list of approximately 150 addresses, to distribute the final rules to stakeholders when they become effective. Division of EMS staff will receive email notification of the rule changes and attend section briefings regarding the implementation policy and procedures. During its meetings, the EMFTS Board receives regular updates about EMS rules.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

- a. Identify the scope of the impacted business community;**
- b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
- c. Quantify the expected adverse impact from the regulation.**

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

- a. The scope of the business community includes approximately 100 smaller hospitals and in-patient rehabilitation facilities and approximately 102 private ambulance companies. The primary nature of the adverse impact is time for compliance; however, failure to comply with RC section 4765.06 will result in ineligibility to receive grants awarded by the State Board of EMFTS under RC section 4765.05.
- b. The nature of the financial impact of this rule on small hospitals and in-patient rehab facilities would be measured in time to enter medical record data into the clinical data systems. It is presumed that most of this activity is performed by medical records technicians who, according to the Bureau of Labor Statistics (www.bls.gov), earn a median \$18.29/hour. Based on 18 years of data in the Ohio Trauma Registry, one of the clinical data systems governed by this rule, these small facilities will be required to submit data on fewer than 10 patients per month. Because these facilities are not trauma centers, the patients they treat are not complex, creating a data entry time of approximately 15 minutes per record. This creates a compliance time of approximately 150 minutes per month at a cost of \$45.72 per month (\$549/year). Additionally, 10-15 of these facilities will incur no adverse impact as they do not treat any trauma victims and will not be subject to this rule. Failure to comply with RC section 4765.06 will prevent hospitals from being eligible to receive research grants. Fewer than 10 of these grants are awarded each year, with an average award of approximately \$115,000.
- c. The adverse impact of this rule on the private ambulance services in Ohio is extremely small. The information gathered by the EMS Incident Reporting System (EMSIRS), one of the clinical data systems governed by this rule, is already collected by the services as part of their patient billing process. Time for compliance is comprised of creating an export file of the already collected information and submitting it to EMSIRS, which takes approximately 15 minutes per quarter, or 1 hour per year. According to the Bureau of Labor Statistics (www.bls.gov), median pay for paramedics who may be performing this task is \$15.71/hour. This creates a cost of compliance of \$15.71 per year. Additionally, all private ambulance services bill for their services, and some billing companies provide data submission services gratis to their client EMS agencies. EMS cannot provide cost estimates for such

arrangements. Failure to comply with RC section 4765.06 will prevent ambulance services from being eligible to receive training and equipment grants. The average annual award is for \$4,500.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The clinical data systems were created in RC section 4765.06 to allow the State Board of EMFTS to oversee the provision of EMS and trauma care to the citizens of Ohio. The collection of patient care data is the only method to determine if all citizens are receiving appropriate EMS and trauma care throughout Ohio. Declaring entities ineligible to receive grants created in RC section 4765.05 is considered not only a fair incentive to remain compliant with RC section 4765.06, but also ensures that taxpayer money is not given to entities that are not in compliance with the RC.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

To ensure that all citizens are receiving appropriate EMS and trauma care, no provider of such services can be exempted from this regulation. No alternative means of compliance exist, but the methods in place are designed with the smallest, rural volunteer EMS agencies in mind; therefore, they are as simple and as unobtrusive as possible.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Policies have long existed to provide all entities required to submit data with adequate warning of non-compliance before moving to sanctions. These include friendly reminders of the need for compliance by e-mail or telephone, offers of assistance in training on the clinical data systems, and a policy of escalating warnings. Over the past decades, sanctions have only been levied against entities that have been non-compliant over multiple regular deadlines.

18. What resources are available to assist small businesses with compliance of the regulation?

Web-based data entry systems are provided to any entity wishing to avoid the expense of purchasing its own database systems. These are available on the Ohio Department of Public Safety's *Data Center* website (<http://www.ems.ohio.gov/data-center.aspx>) 24 hours a day, 7 days a week and are free of charge.

Additionally, training in use of these systems is provided to EMS agencies, hospitals and inpatient rehabilitation facilities. These training sessions can be held at the EMS station,

hospital or rehab facility, over the phone, by webinar, or at the Ohio Department of Public Safety. The location is the trainee's choice, and the sessions are free of charge.

The Division of EMS's Web site contains a "Small Business Regulatory Impact" section (<http://www.ems.ohio.gov/laws.aspx>) with links to R.C. 4766. and R.C. 4765., O.A.C. 4766, and O.A.C. 4765, CSIO, and JCARR. Rules scheduled for review, open for public comment, proposed, and recently adopted are posted at the Web site, along with public comment and public hearing information and email links for the ODPS Rules Administrator and Division of EMS rules personnel.

Each unit of the EMS Web page, including the *Trauma System* Web page (<http://www.ems.ohio.gov/trauma-system.aspx>), includes links to the laws and rules associated with that topic, along with an overview section. The *Agency Directory* at the EMS Web site (<http://www.ems.ohio.gov/about-directory.aspx>) includes the email addresses, telephone numbers, including a toll free number (1-800-233-0875), and the names of EMS staff, including the Trauma & Research staff. The Trauma & Research staff members are available by phone and by email and can be reached via the *Ask EMS* (ASKEMS@dps.ohio.gov) email address available at the EMS Web site and via the Trauma System Section (DPS Trauma or trauma@dps.ohio.gov) email address.

Trauma & Research staff members attend and present information about data reporting at conferences including those conducted by the Ohio Association of Emergency Medical Services (OAEMS).